DMB

Display Date 10-27-99
Publication Date 10-28-99
Certifier

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 801, 878, and 880

[Docket No. 98N–0313]

Surgeon's and Patient Examination Gloves; Reclassification; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to January 27, 2000, the comment period for the proposed rule that appeared in the **Federal Register** of July 30, 1999 (64 FR 41710) . The proposed rule would reclassify all surgeon's and patient examination gloves as class II medical devices. The agency is taking this action in response to two requests for extension of the comment period. This extension of the comment period is intended to allow interested persons additional time to submit comments on the proposed rule.

DATES: Written comments by January 27, 2000.

ADDRESSES: Submit written comments on the proposed rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Donald E. Marlowe, Center for Devices and Radiological Health (HFZ–100), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4777.

SUPPLEMENTARY INFORMATION:

I. Extension of Comment Period

In the **Federal Register** of July 30, 1999, FDA published a proposed rule to reclassify all surgeon's and patient examination gloves as class II medical devices. FDA is soliciting comments and information from interested persons concerning the reclassification of these devices into four categories (powdered surgeon's gloves, powder-free surgeon's gloves, powdered patient examination gloves, and powder-free patient examination gloves), and it proposed special controls consisting of a ''Medical Glove Guidance Manual'' and labeling requirements that address protein and powder content.

FDA received one request from a manufacturer of medical gloves and another request from a voluntary standard setting organization to extend the comment period an additional 90 days. The manufacturer and the voluntary standard setting organization requested additional time to allow the American Society for Testing and Materials (ASTM), a voluntary standard setting organization, to complete its balloting for revisions of its standards to include a recommended maximum powder limit in its standards for latex surgeon's gloves, latex patient examination gloves, polyvinyl medical gloves, and nitrile patient examination gloves. The manufacturer and the voluntary standard setting organization wanted the additional time to allow FDA and others to consider ASTM's recommendations along with FDA's proposal. In response to the letters, FDA is extending the comment period for 90 additional days. Elsewhere in this issue of the **Federal Register**, FDA is announcing an extension of the comment period for the draft guidance entitled ''Medical Glove Guidance Manual.''

II. Comments

Interested persons may, on or before January 27, 2000, submit to the Dockets Management Branch (address above) written comments regarding the proposed rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to

be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 10/21/99

October 21, 1999

Margaret M. Dotzel
Acting Associate Commissioner
for Policy

[FR Doc. 99–???? Filed ??–??–99; 8:45 am]

BILLING CODE 4160–01–F

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Michael D. Bell